

AMENDED IN SENATE JUNE 13, 1996

AMENDED IN SENATE MAY 9, 1996

AMENDED IN ASSEMBLY APRIL 11, 1996

CALIFORNIA LEGISLATURE—1995–96 REGULAR SESSION

ASSEMBLY BILL

No. 2915

Introduced by Assembly Member Friedman

February 22, 1996

An act to add Article 1 (commencing with Section 104145) to Chapter 2 of Part 1 of Division 103 of the Health and Safety Code, and to repeal Section 9 of Chapter 661 of the Statutes of 1993, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 2915, as amended, Friedman. Breast cancer research.

Existing law, in an uncodified statute (Sec. 9, Ch. 661, Stats. 1993, as amended by Sec. 2, Ch. 483, Stats. 1994), creates a Breast Cancer Research Program and requests the University of California to administer the program as a comprehensive grant and contract program to support research efforts into the cause, cure, treatment, earlier detection, and prevention of breast cancer. It states intent of the Legislature that the University of California establish a Breast Cancer Research Council with specified membership and duties.

This bill would repeal these uncodified provisions of law and would reenact them, as amended, in a codified statute. It would ~~request the University of California and the council to work in close collaboration with the Breast Cancer Early~~

~~Detection Program~~, revise provisions governing membership in the council and impose funding eligibility limitations on council members, as specified, and expand the groups of persons who may be recruited for participation in a peer review panel, among other things.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Article 1 (commencing with Section 104145) is added to Chapter 2 of Part 1 of Division 103 of the Health and Safety Code, to read:

Article 1. The Breast Cancer Research Program

104145. (a) The Legislature hereby requests the University of California to establish and administer the Breast Cancer Research Program, which is created by this act, as a comprehensive grant and contract program to support research efforts into the cause, cure, treatment, earlier detection, and prevention of breast cancer. It is the intent of the Legislature that this program incorporate the principles and organizational elements specified in this act, including, but not limited to, a research program office with a director and other necessary staff, a Breast Cancer Research Council, and research review panels.

(b) For the purposes of this section:

(1) "Breast cancer research" includes, but is not limited to, research in the fields of biomedical science and engineering, the social, economic and behavioral sciences, epidemiology, technology development and translation, and public health.

(2) "Council" means the Breast Cancer Research Council.

(3) "Grantee" means any qualifying public, private, or nonprofit agency or individual, including, but not limited to, colleges, universities, hospitals, laboratories, research institutions, local health departments, voluntary health

1 agencies, health maintenance organizations,
2 corporations, students, fellows, entrepreneurs, and
3 individuals conducting research in California.

4 (4) “Program” means the Breast Cancer Research
5 Program.

6 (5) “University” means the University of California.

7 (c) It is the intent of the Legislature that this program
8 be administered pursuant to the following principles:

9 (1) The university ~~is requested to~~ *shall* work in close
10 collaboration with the council and seek the consent of the
11 council before taking an action different from the action
12 recommended by the council.

13 (2) The council shall develop the strategic objectives
14 and priorities of the program, actively participate in the
15 overall management of the program, and make final
16 recommendations on which research grants should be
17 funded based on the research priorities established for
18 the program and the technical merits of the proposals as
19 determined by peer review panels.

20 (3) The program shall fund innovative and creative
21 research, with a special emphasis on research that
22 complements, rather than duplicates, the research
23 funded by the federal government and other entities.

24 (4) The university ~~should~~ and the council shall work in
25 close collaboration with the Breast Cancer Early
26 Detection Program.

27 (5) All research funds shall be awarded on the basis of
28 the research priorities established for the program and
29 the scientific merit of the proposed research, as
30 determined by an open, competitive peer review process
31 that ensures objectivity, consistency, and high quality. All
32 investigators, regardless of affiliation, shall have equal
33 access and opportunity to compete for program funds.

34 (6) The peer review process for the selection of
35 research grants awarded under this program shall be
36 generally modeled on that used by the National Institutes
37 of Health in its grantmaking process.

38 (7) An awardee shall be awarded grants for the full
39 cost, both direct and indirect, of conducting the
40 sponsored research consistent with those federal

1 guidelines governing all federal research grants and
2 contracts. All intellectual property assets developed
3 under this program shall be treated in accordance with
4 state and federal law.

5 (8) In establishing its research priorities, the council
6 shall consider a broad range of cross-disciplinary breast
7 cancer research, as defined in paragraph (1) of
8 subdivision (b), including, but not limited to, research
9 into the cause, cure, and prevention of breast cancer;
10 translational and technological research, including
11 research regarding the development and translation of
12 technologies of earlier detection; research regarding the
13 cultural, economic, and legal barriers to accessing the
14 health care system for early detection and treatment of
15 breast cancer; and research examining the link between
16 breast cancer and environmental factors, including both
17 natural and industrial chemicals, estrogen imitators, and
18 electromagnetic fields.

19 (d) It is the intent of the Legislature that the
20 university, as lead agency, do all of the following:

21 (1) Establish the Breast Cancer Research Council in
22 accordance with the following:

23 (A) The council shall consist of at least 13 and no more
24 than 15 members representing a range of expertise and
25 experience, appointed by the President of the University
26 ~~of California from nominations solicited from and~~
27 ~~submitted by relevant organizations, as follows: of~~
28 *California. Individuals and organizations may submit*
29 *nominations to the council, and the University of*
30 *California shall solicit nominations from relevant*
31 *organizations and individuals. The council shall be*
32 *comprised of the following members:*

33 (i) Four members from breast cancer survivor and
34 breast cancer-related advocacy groups, including, but not
35 limited to, the California Breast Cancer Organizations
36 (CABCO).

37 (ii) Four members drawn from the ranks of scientists
38 or clinicians, including one from an independent
39 research university in California. The scientists shall have
40 expertise covering the various fields of scientific

1 endeavor, including, but not limited to, the fields of
2 biomedical research and engineering, social, economic,
3 and behavioral research, epidemiology, and public
4 health.

5 (iii) Two members from nonprofit health
6 organizations with a commitment to breast cancer
7 research and control.

8 (iv) One member who is a practicing breast cancer
9 medical specialist.

10 (v) Two members from private industry with a
11 ~~demonstrated~~ commitment to breast cancer research and
12 control, including, but not limited to, entrepreneurs, or
13 persons from the science or high technology industry or
14 persons from the health care sector.

15 (vi) One ex officio, nonvoting member from the
16 Breast Cancer Early Detection Program.

17 (B) If the president appoints more than 13 members,
18 it is the intent of the Legislature that the proportional
19 representation remain substantially the same as set forth
20 in subparagraph (A).

21 (C) Members shall serve without compensation, but
22 may receive reimbursement for travel and other
23 necessary expenses actually incurred in the performance
24 of their official duties. Any member of the Breast Cancer
25 Research Council shall be ineligible to *apply for or*
26 receive funding for breast cancer research from the
27 Breast Cancer Research Program during his or her
28 *three-year* term of service on the council, *whether or not*
29 *served in full*.

30 (D) Membership shall be staggered in such a way as to
31 maintain a full council while ensuring a reasonable
32 degree of continuity of expertise and consistency of
33 direction.

34 (2) Provide overall coordination of the program.

35 (3) Provide staff assistance to the program and
36 council.

37 (4) Develop administrative procedures relative to the
38 solicitation, review, and awarding of grants to ensure an
39 impartial, high quality peer review system.

1 (5) Recruit and supervise research review panels. The
2 membership of these panels shall vary depending on the
3 subject matter of the proposals and the review
4 requirements, and shall draw on the most qualified
5 individuals. The work of the review panels shall be
6 administered pursuant to policies and procedures
7 established for the implementation of the program. In
8 order to avoid conflicts of interest and to ensure access to
9 ~~qualified reviewers, it is the intent of the Legislature that~~
10 ~~the university utilize reviewers from outside the state~~
11 ~~unless reviewers with expertise in particular research~~
12 ~~grant proposals are only available within the state. When~~
13 ~~qualified reviewers, the university may utilize reviewers~~
14 ~~not only from California but also from outside the state.~~
15 When serving on review panels, institutions,
16 corporations, or individuals who have submitted grant
17 applications for funding by this program shall be
18 governed by conflict-of-interest provisions consistent
19 with the National Institutes of Health Manual (Chapter
20 4510 (item h)), and any applicable conflict-of-interest
21 provisions in state law.

22 (6) Provide for periodic program evaluation to ensure
23 that research funded is consistent with program goals.

24 (7) Maintain a system of financial reporting and
25 accountability.

26 (8) Provide for the systematic dissemination of
27 research results to the public and the health care
28 community, and provide for a mechanism to disseminate
29 the most current research findings in the areas of cause,
30 treatment, cure, earlier detection, and prevention of
31 breast cancer, in order that these findings may be applied
32 to the planning, implementation, and evaluation of the
33 breast cancer-related programs of the State Department
34 of Health Services, including the Breast Cancer Early
35 Detection Program authorized by this act.

36 (9) Develop policies and procedures to facilitate the
37 translation of research results into commercial, alternate
38 technological, and other applications wherever
39 appropriate and consistent with state and federal law.

(10) Transmit annually on or before each December 31, a report to the Legislature on grants made, grants in progress, program accomplishments, and future program directions. Each report shall include, but not be limited to, the following information:

(A) The number and dollar amounts of research grants, including the amount allocated to indirect costs.

(B) The subject of research grants.

(C) The relationship between federal and state funding for breast cancer research.

(D) The relationship between each project and the overall strategy of the research program.

(E) A summary of research findings including discussion of promising new areas.

(F) The institutions and campuses receiving grant awards.

In addition, the first annual report shall include an evaluation and recommendations concerning the desirability and feasibility of requiring for-profit grantees to compensate the state in the event that a grant results in the development of a profit-making product. This evaluation shall include, but not be limited to, the costs and benefits of requiring a for-profit grantee to repay the grant, to provide the product at cost to Medi-Cal and other state programs serving low-income breast cancer patients, and to pay the state a percentage of the royalties derived from the product.

(e) It is the intent of the Legislature that no more than 5 percent of the allocation to the university be used for the purposes of administration of this program.

(f) It is the intent of the Legislature that the responsibilities of the council shall include, but not be limited to, the following:

(1) Development and review of the strategic objectives and research priorities of the program.

(2) Delineation of resource allocation across the various priorities established for the program.

(3) Participation in periodic program and financial review, including the report transmitted pursuant to paragraph (10) of subdivision (d).

1 (4) Development and review of guidelines to ensure
2 fairness, neutrality, and adherence to the principles of
3 merit and quality in the conduct of the program.

4 (5) Development of appropriate linkages to
5 nonacademic entities, including, but not limited to,
6 voluntary organizations, health care delivery systems,
7 industry, government agencies, research entrepreneurs,
8 and public officials.

9 (6) Development and review of criteria and standards
10 for granting awards.

11 (7) Oversight and review of the request for
12 applications (RFA).

13 (8) Review of research review panel reports and
14 recommendations for grant awards.

15 (9) Making of final recommendations on which grants
16 are to be awarded.

17 (10) Development and review of oversight
18 mechanisms for the dissemination of research results.

19 (11) Development and review of policies and liaison
20 programs to facilitate the translation of research results
21 into commercial, alternate technological, or other
22 applications wherever appropriate.

23 (12) Establishment of its own internal rules of
24 operation.

25 (13) Participation in the identification and
26 recruitment of breast cancer advocates and survivors,
27 clinicians, scientists, and persons from the science, high
28 technology, or health care sector with relevant expertise
29 for possible participation in a peer review panel. The
30 council may propose to assign a member of the council to
31 sit as a nonvoting member of the peer review panels.

32 SEC. 2. Section 9 of Chapter 661 of the Statutes of
33 1993, as amended by Section 2 of Chapter 483 of the
34 Statutes of 1994, is repealed.